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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,380	06/22/2001	Isamu Takase	1200-0101P	5689
2292	7590	02/07/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			COBANOGLU, DILEK B	
			ART UNIT	PAPER NUMBER
			3626	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/886,380	TAKASE, ISAMU	
	Examiner	Art Unit	
	Dilek B. Cobanoglu	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 June 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 22 June 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

1. Claims 1-9 have been examined.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(a) as being unpatentable by Brown (U.S. Patent No. 5,960,403).

A. As per claim 1, Brown discloses a therapy management system having a host computer on the side of a physician and a computer on the side of a patient (Brown; abstract) wherein the physician side host computer comprises at least:

- (i) a display means to display the information of therapy instructions including the name of the patient (Brown; col.5, lines 57-61), the treatment data of the patient, and the instructions from the physician (Brown; col.8, lines 14-33);
- (ii) a recording means to record the name of the patient, the treatment data of the patient, and the instructions from the physician (Brown; col.5, lines 57-61);

- (iii) a memory means to store the name of the patient (Brown; col.5, lines 57-61), the treatment data of the patient, and the instructions from the physician (Brown; col.11, lines 57-63);
- (iv) a transmission means to transmit the information of therapy instructions to the patient side computer (Brown; col.3, lines 48-51 and col.4, lines 2-4);
- (v) a receiving means to receive the information of patient's report result transmitted by the patient side computer (Brown; col.3, lines 59-63);
- (vi) a display means to display the information of patient's report result (Brown; col.7, lines 5-11);
- (vii) a memory means to store the information of patient's report result (Brown; col.9, lines 40-47);
- (viii) a memory means to store the information of the patient's past medical history (Brown; col.8, lines 14-33);
- (ix) a memory means to store the information of patient's past report result (Brown; col.9, lines 40-47);
- (x) a memory means to store the information of updated therapy instructions (Brown; col.4, lines 5-14); and
- (xi) a transmission means to transmit the information of updated therapy instructions to the patient side computer (Brown; col.16, lines 46-49),

while the patient side computer comprises at least:

- (xii) a receiving means to receive the information of therapy instructions (Brown; col.4, lines 2-4) including the name of the patient (Brown; col.5, lines 57-61), the treatment data of the patient, and the instructions from the physician (Brown; col.8, lines 14-33);
- (xiii) a memory means to store the thus received information of therapy instructions (Brown; col.11, lines 57-63) including the name of the patient (Brown; col.5, lines 57-61), the treatment data of the patient, and the instructions from the physician (Brown; col.8, lines 14-33);
- (xiv) a display means to display the thus received information of therapy instructions including the name of the patient (Brown; col.5, lines 57-61), the treatment data of the patient, and the instructions from the physician (Brown; col.8, lines 14-33);
- (xv) a display means to display the actions to be taken by the patient in compliance with the instructions from the physician (Brown; col.17, lines 27-34);
- (xvi) a notifying means to notify the patient of the actions to be taken in compliance with the instructions from the physician (Brown; col.10, line 62 to col. 11, line 1);

- (xvii) a recording means to record the actions actually taken by the patient in compliance with the instructions from the physician (Brown; col.3, lines 59-63);
- (xviii) a memory means to store the recorded content (Brown; col.8, lines 48-51);
- (xix) a recording means to record the treatment data obtained by measurement (Brown; col.3, lines 38-42);
- (xx) a display means to display the treatment data obtained by measurement (Brown; col.5, lines 43-51);
- (xxi) a memory means to store the treatment data obtained by measurement (Brown; col.8, lines 48-51); and
- (xxii) a transmission means to transmit the stored information of the patient's report result to the host computer on the side of the physician (Brown; col.9, lines 39-47).

B. As per claim 2, Brown discloses a therapy management system as described in claim 1 wherein the patient side computer comprises a portable terminal (Brown; col.13, lines 27-32).

C. As per claim 4, Brown discloses a therapy management system as described in claim 1, wherein the physician side host computer comprises at least the steps (i) to (xviii) described in claim 1 and

- (i) a display means to display the time of meal; a setting means through which one can set the time of meal; a memory means to

store the time of meal thus set; a notifying means to notify the time of meal thus set; an altering means through which one can alter the set time of meal; a display means to display the time of meal thus altered; a memory means to store the time of meal thus altered (Brown; col.8, lines 14-33);

(ii) a display means to display the diet unit of a meal (Brown; col.17, line 67 to col.18, line4)

(iii) a setting means through which one can set the diet unit of a meal (Brown; col.17, line 67 to col.18, line4);

(iv) a memory means to store the diet unit of a meal thus set (Brown; col.17, line 67 to col.18, line4);

(v) a display means to display a time for blood sugar measurement (Brown; col.14, lines 47-49);

(vi) a memory means to store the time for blood sugar measurement (Brown; col.8, lines 14-33);

(vii) a notifying means to notify or signal the time for blood sugar measurement (Brown; col.8, lines 14-33);

(viii) a recording means to record a blood sugar level obtained by measurement (Brown; col.8, lines 14-33);

(ix) a display means to display the blood sugar level thus recorded (Brown; col.4, lines 61-65);

- (x) a memory means to store the blood sugar level thus recorded (Brown; col.16, lines 13-15);
- (xi) a display means to display an exercise amount (Brown; col.17, line 67 to col. 18, line 4);
- (xii) a recording means to record an amount of exercise actually performed (Brown; col.17, line 67 to col. 18, line 4);
- (xiii) a memory means to store the record (Brown; col.8, lines 48-51); and
- (xiv) a transmission means to transmit the stored information of the patient's report result to the host computer on the side of the physician (Brown; col.9, lines 39-47).

The sections (i) to (xviii) described in claim 1 are rejected as addressed above in the rejection of claim 1 and incorporated herein.

D. As per claim 5, Brown discloses a therapy management system as described in claim 2 wherein the portable terminal (Brown; col.13, lines 27-32) on the side of the patient comprises at least the steps described in claim 4 precisely; therefore claim 5 is rejected as addressed above in the rejection of claim 4 and incorporated herein.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (U.S. Patent No. 5,960,403) in view of Heinonen et al. (U.S. Patent No. 5,772,586).

A. As per claim 3, Brown discloses a therapy management system as described in claim 1 (Brown; abstract) wherein the patient side computer comprises a portable telephone unit.

Brown fails to expressly teach a portable telephone unit, per se, since it appears that Brown is more directed to a patient computing device. However, this feature is well known in the art, as evidenced by Heinonen et al.

In particular, Heinonen et al. discloses a method for monitoring the health of a patient, wherein the communications device may be any device, which is suitable for wireless communications such a mobile phone (Heinonen et al.; col. 2, lines 42-50).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined health management process control system disclosed by Brown within the communications device such a mobile phone taught by Heinonen et al., with the motivation of the patient can transmit his measurement results to the data processing system available his doctor,

regardless of where the patient is at the moment (Heinonen et al.; col. 2, lines 42-47).

6. Claims 6 to 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (U.S. Patent No. 5,960,403) in view of Beckers (U.S. Patent No. 5,019,974).

A. As per claim 6, Brown discloses a therapy management system as described in claim 2 wherein the portable terminal on the side of the patient (Brown; col. 13, lines 27-32) comprises at least the steps (i) to (xiv) described in claim 4 and

- (i) a display means to display the time for dispensing a medicine;
- (ii) a memory means to store a time for dispensing a medicine (Brown; col. 14, lines 61-62);
- (iii) a notifying means to notify the time for dispensing a medicine;
- (iv) a recording means to record the result of the dispensation of a medicine (Brown; col. 9, lines 40-47);
- (v) a display means to display the result of the dispensation of a medicine (Brown; col. 11, lines 22-34);
- (vi) a memory means to store the result of the dispensation of a medicine (Brown; col. 9, lines 40-47);
- (vii) a display means to display a time of insulin injection;
- (viii) a memory means to store the time for insulin injection;

- (ix) a notifying means to notify the time for insulin injection;
- (x) a recording means to record the result of insulin injection;
- (xi) a display means to display the result of insulin injection;
- (xii) a memory means to store the result of insulin injection;

(a) Brown fails to expressly teach to display and notify time for dispensing a medicine *per se*, since it appears that Brown is more directed to record, display and store of the result of the dispensation of a medicine. However, this feature is well known in the art, as evidenced by Beckers. In particular, Beckers discloses a diabetes management system and apparatus, wherein recorded programme to display at appropriate times the desired treatment or medication and record the information entered by the patient (Beckers; col. 1, lines 33-45).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined health management process control system disclosed by Brown within the recorded programme to display at appropriate times the desired treatment or medication and record the information entered by the patient taught by Beckers, with the motivation of to improve or alter the therapy programme (Beckers; abstract).

(b) Brown also fails to expressly teach to display, store and notify neither the time for insulin injection nor the results of insulin injection per se, since it appears that Brown is more directed to provide information on educational programs, which covers the insulin dosages. However, this feature is well known in the art, as evidenced by Beckers. In particular, Beckers discloses a diabetes management system and apparatus, wherein patient therapy information includes insulin injection times and amounts (Beckers; col. 3, lines 40-45), notify the time for insulin injection (Beckers; col. 3, line 67 to col. 4, line 5), record (Beckers; col. 4, lines 38-39), display (Beckers; col. 4, lines 18-22) and store the result of insulin injection (Beckers; col. 4, lines 38-39). It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined health management process control system disclosed by Brown within the insulin injection times and amounts taught by Beckers, with the motivation of to improve or alter the therapy programme (Beckers; abstract). The steps of (i) to (xiv) of claim 4 are disclosed also in claim 6, therefore those steps are rejected as addressed above in the rejection of claim 4 and incorporated herein.

B. As per claim 7, Brown discloses a patient side computer used for the therapy management system as described in claim 1 to be applied to a diabetic patient (Brown; col. 3, lines 35-42), comprising at least the steps disclosed in claim 6 precisely.

The steps of (i) to (xiv) of claim 4 and steps (i) to (xii) of claim 6 are disclosed also in claim 7, therefore those steps are rejected as addressed above in the rejection of claim 4 and 6 and incorporated herein.

C. As per claim 8, Brown discloses a portable terminal (Brown; col. 13, lines 37-32) for a diabetic patient (Brown; col. 3, lines 35-42) comprising at least: the steps disclosed in claim 8 precisely.

The steps of (i) to (xiv) of claim 4 and steps (i) to (xii) of claim 6 are disclosed also in claim 8, therefore those steps are rejected as addressed above in the rejection of claim 4 and 6 and incorporated herein.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (U.S. Patent No. 5,960,403) in view of Beckers (U.S. Patent No. 5,019,974) as applied to claim 8 above, and further in view of Heinonen et al. (U.S. Patent No. 5,772,586).

A. As per claim 9, Brown discloses a portable telephone unit for a diabetic patient comprising at least the steps of (i) to (xiv) of claim 4 and steps (i) to (xii) of claim 6 are disclosed also in claim 9, therefore those steps are

rejected as addressed above in the rejection of claim 8 and incorporated herein.

Brown and Beckers fail to expressly teach a portable telephone unit, *per se*, since it appears that Brown is more directed to a patient computing device and Beckers is more directed to a monitor including a computer, a display and a keyboard. However, this feature is well known in the art, as evidenced by Heinonen et al. In particular, Heinonen et al. discloses a method for monitoring the health of a patient, wherein the communications device may be any device, which is suitable for wireless communications such a mobile phone (Heinonen et al.; col. 2, lines 42-50). It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined health management process control system disclosed by Brown and diabetes management system and apparatus disclosed by Beckers within the communications device such a mobile phone taught by Heinonen et al., with the motivation of the patient can transmit his measurement results to the data processing system available his doctor, regardless of where the patient is at the moment (Heinonen et al.; col. 2, lines 42-47).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not used arts teach "Patient-operated glucose monitor and diabetes management system" 4,731,726, "Diabetes therapy management system, apparatus and method" 5,216,597, "Medical system and associated method for automatic diagnosis and treatment" 5,415,167, "Medical communication system" 5,462,051, "Patient operated system for testing and recording a biological condition of the patient" 5,501,231, "Analytical system for monitoring a substance to be analyzed in patient-blood" 5,507,288.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dilek B. Cobanoglu whose telephone number is 571-272-8295. The examiner can normally be reached on 8-4:30.
10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DBC
Dilek B. Cobanoglu
Art unit 3626

Joseph Thomas
JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER